PMUSA Clinical Evaluation Clinical Process:
Cigarette accountability at MDSPS investigative sites

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The investigative site Pharmacy and the monitoring Clinical Research Associate will independently reconcile the total number of cigarette packs shipped to the site, the number of cigarette packs dispensed during a study, and the number of unopened packs remaining at the end of a study's clinical conduct.

For Confinement Periods:

1. At the end of each 24-h interval (i.e., 07:00 to 07:00 or study-specific daily smoking interval [e.g., 07:00 to 23:00 for controlled smoking conditions]) the investigative site Pharmacy will reconcile the ClinQuick™ system-documented number of cigarettes allotted, cigarettes dispensed, and butts returned for each subject.

For Ambulatory Periods:

1. At each subject visit, the investigative site Pharmacy will document in the EP-90™ system the number of full cigarette packs dispensed and the number of empty cigarette packs returned.

   Conventional (comparator) cigarettes may be redispensed once accounted for. Redispensation of investigational cigarettes will be decided by PMUSA on a study-by-study basis.

2. The MDS Clinical Study Manager will be responsible for comparing at each subject visit the daily consumption by pharmacy dispensation/return records with that by uploaded WatchPC™ data.

   a. If there is a discrepancy > 15%, the Study Manager will be responsible for querying the subject within 2 weeks about the reason, documenting subject's response, and counseling the subject re improved compliance.

   b. The MDS Study Manager will discuss with the PMUSA Study Manager any subjects who have repeated discrepancies > 15%.

N.B.: *Each conventional carton contains 10 packs; each conventional pack contains 20 cigarettes. Deviations from this will be noted.*